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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,934	02/21/2006	Bent Piil Pedersen	10326.204-US	1893

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EXAMINER	
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ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
06/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/524,934	PEDERSEN ET AL.	
	Examiner	Art Unit	
	C. SAYALA	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, applicant recites a last step of preparing, but omits to recite a definition of such preparation rendering the metes and bounds of this claim unclear. Preparation can entail any number of processes, and it is not clear if applicant intends all that is applicable here to be part of this property. Clarification is required to assess whether such processes are supported by the specification under 35 USC 112, paragraph one.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19, 21, 23, 28-30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldman et al. (US Patent 3857966) taken in light of Loosen et al. (US Patent 5356637).

Feldman et al. teach a method of producing a food composition which includes the hydrolysis of fish protein by reacting the protein first with an alkaline protease and then with a neutral protease to obtain such benefits as protein that is soluble and bland so that it can be used in food substrates without adversely affecting their clarity and consistency of texture. See col. 2, line 8, Example III.

The protein is inactivated after completion of the reaction by raising the temperature. See col. 4, lines 48-54, col. 1, lines 58-65.

Both the enzymes are obtained preferably from Bacillus. See col. 3, lines 48-51 and col. 4, lines 11-30. Note that the patent teaches "Alcalase" as the alkaline protease which was known to be derived from *Bacillus licheniformis*, at the time the invention was made. See Loosen et al. at col. 4, lines 34-35 cited here as an evidentiary reference to this fact.

With regard to claim 28, the protein is centrifuged after hydrolysis, to separate the solids. With regard to claim 29, use of a centrifuge meets the necessary "separator". With regard to drying the product, the patent teaches freeze-drying and drying. Col. 2, lines 32-34, 50-55, 63-68; col. 5, lines 8-11, Example III; col. 1, line 66.

Note that the disclosure of Feldman is directed to food and preparing man is considered the epitome of an animal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20, 24, 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. taken with Simpson et al. (Food Chemistry, vol. 61, No. ½, pages 131-138, 1998) in view of Faith Jr. et al. (US Patent 3697285).

Feldman is as described above. Feldman teaches using alkaline and neutral proteases to produce a fish hydrolyzate that is a bland, soluble, clear and heat stable protein for use in foods. Feldman does not teach the removal of oil or that the fish is raw.

Simpson has been used for the following disclosure (page 131, col. 2):

"…the potential of seafood protein hydrolysates as food flavourants and protein supplements has not been fully exploited. Fish protein hydrolysates have been shown to be very good sources of bacterial peptones, and are currently used for production of milk substitutes for calves and weaning pigs, fish feed, pet food, and as a flavouring agent in countries like Japan, France, Norway, and the United States (Gildberg, 1993 and Vecht-Lifshitz et al., 1990). Studies on the effect of commercial fish protein hydrolysates on mouse lymphocytes also revealed that certain compounds in the hydrolysate promoted immunostimulation, while feeding of domestic animals with fish silage hydrolysate reduced their disease frequency (Vinot et al., 1989 and Gildberg, 1993). Several proteases have been used for the production of these hydrolysates. These include papain, ficin, bromelin, trypsin, pancreatin, alcalase, and pronase

(Venugopal and Shahidi, 1995 and Gildberg, 1993). However, the product quality varies with the nature of the enzyme and processing conditions employed. For instance, while pepsin proved to be more effective at solubilizing proteins in threadfin bream, pronase formed a product with less bitterness (Hevia et al., 1976 and Venugopal and Lewis, 1981). The use of other enzymes capable of degrading such bitter peptides, would eliminate this problem (Sugiyama et al., 1991). Other studies with fish hydrolysates indicated that hydrolysates prepared with *Streptomyces* proteases had better nutritional value for rats than casein, whereas hydrolysates formulated with *Bacillus subtilis* protease were inferior to casein probably due to an imbalance of the essential amino acids (Higashi et al., 1965)."

Thus the prior art recognized the use and need of various enzymes in order to prepare a suitable protein hydrolyzate from fish that was of good quality, not bitter and/or solubilized. The Simpson reference also recognizes that fish protein hydrolyzates have been used in prior art for pigs, fish feed, calves and pet foods at the time the invention was made. Simpson provides the motivation to do what Feldman has done in order to obtain a soluble, bland and heat stable protein.

The Faith reference teaches the hydrolysis of fish proteins and teaches that after the enzymatic hydrolysis, the resulting slurry of protein solution, oil and solids is then separated into its components by filtering and then centrifuging. The solution is then dried by spray or air or *drum-drying* to obtain a soluble fish protein. See col. 3, line 74 to col. 5, line 6. Note example 1, which teaches hydrolyzing raw fish. To start the hydrolysis using Feldman's disclosure and with raw fish would not require more than ordinary skill with the reasonable expectation that a soluble, bland fish protein hydrolysate would result. Simpson's disclosure of fish feed renders obvious the variety of fish recited at claim 33.

4. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. taken with Simpson et al. (Food Chemistry, vol. 61, No. ½, pages 131-138, 1998) in view of Freeman et al. (US Patent 4473589) .

Feldman is discussed above, as is Simpson. The Feldman reference does not disclose that the protein hydrolyzate is used in a method to feed animals. Feldman teaches obtaining a soluble and bland protein hydrolysate by using alkaline and neutral proteases. Simpson recognizes that at the time the invention was made protein hydrolysates were being used to feed pigs, calves, fish, etc. and also discloses that the proteins obtained were bitter, low quality and not soluble. Clearly, Feldman's disclosure solves such a problem. Freeman teaches the use of a hydrolyzed fish protein as feed supplements. See col. 1, line 17, col. 2, line 8. The Simpson reference also recognizes that fish protein hydrolyzates have been used in prior art for pigs, fish feed, calves and pet foods at the time the invention was made. Such disclosures render obvious feeding animals with hydrolyzed proteins as obtained from Feldman's invention and based on the fact that feeding animals with fish protein hydrolysates was already being practiced in the art at the time the invention was made.

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. taken with Simpson et al. (Food Chemistry, vol. 61, No. ½, pages 131-138, 1998) in view of Ikeda et al. (US Patent 4036993) and FR 2352498.

Feldman and Simpson are as discussed above. Feldman does not show that the fish meat was not heated above 70^0C before hydrolysis. Ikeda teaches elevating the

temperature to above 60^0C, which would include the range 60-70^0C. Freeman teaches a temperature range 120-170^0F, which includes a temperature of about 76^0C at its highest. FR '498 teaches heating fish to 40^0C. before being subjected to enzymatic action. What such temperatures show is that while temperatures below 70^0C were in fact in use at the time the invention was made, the ranges shown render obvious that determining such temperatures are within the ambit of routine skill based on the enzyme used, the type of protein and hydrolysis required.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. taken with Simpson et al. (Food Chemistry, vol. 61, No. ½, pages 131-138, 1998) in view of Xu et al. (US Pub. 2002/0004085).

Feldman and Simpson are as discussed above with respect to claim 19. Feldman does not disclose that the neutral protease is obtained from *Bacillus amyloliquefaceins.* See ¶ [0081] in Xu et al. that teaches GLUTENASE or NEUTRASE as enzymes that are neutral proteases obtained from *Bacillus amyloliquefaceins.* To use such enzymes as the neutral protease of Feldman et al. would have been prima facie obvious.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. taken with Simpson et al. (Food Chemistry, vol. 61, No. ½, pages 131-138, 1998) in view of Blinkovsky et al. (US Patent 6187578) and Olsen (US Patent 4324805).

Feldman and Simpson are as described above. Claims 26 and 27 recite the degree of hydrolysis to which the fish meat is hydrolyzed. Feldman does not disclose this feature.

Blinkovsky teaches the following @ col. 1, lines 39-47 and col. 2, lines 16-23:

> Enzymatic hydrolysis processes aim at obtaining a high degree of hydrolysis (DH), and this is usually attained using a complex of unspecific acting proteolytic enzymes (i.e., unspecific acting endo- and exo-peptidases). For example, WO 94/25580 describes a method for hydrolyzing proteins by use of an unspecific acting enzyme preparation obtained from *Aspergillus oryzae*. Specific acting proteolytic enzymes have not been used for this purpose because such enzymes only lead to an inadequate degree of hydrolysis.
>
> The production of protein hydrolysates with desirable organoleptic properties and high degrees of hydrolysis generally requires the use of a mixture of peptidase activities. It would be desirable to provide a single component peptidase enzyme which has activity useful for improving the organoleptic properties and degree of hydrolysis of protein hydrolysates used in food products either alone or in combination with other enzymes.

Olsen discloses @ col. 3, line 48 to col. 4, line 9:

> The degree of hydrolysis (DH) is defined by the equation:
> DH= Number of peptide bonds cleaved/Total number of peptide bonds x100%
>
> Reference is made to J. Adler-Nissen, J. Agric. Food Chem., Vol. 24, No. 6, (1976) page 1090-1093 where a more detailed discussion of the definition of DH appears.
>
> The number of the peptide bonds cleaved can be measured by means of the ninhydrin method. The ninhydrin method is described in Moore, S., Stein, W. H., "Photometric Ninhydrin Method for use in the Chromatography of Amino Acids", J. Biol. Chem., 176, 367-388 (1948).
>
> The DH can also be determined if the course of hydrolysis is followed by means of the pH-STAT method, as described in Jacobsen, S. F., Leonis, J. Linderstrom-Lang, K., Ottesen, M.,

"the pH-STAT and its use in Biochemistry", in Glick, D., (edit.), "Methods of Biochemical Analysis", Vol. IV, pp. 171-210, Interscience, Publishers Inc., New York (1957).

As is apparent from the above the DH plays an important role in the invention, inasmuch as the hydrolysis is controlled by means of the DH; only when DH has reached a critical value, the hydrolysis may be terminated. The DH is, so to speak, the main parameter of the hydrolysis.

Based on these teaching references it would have been obvious to select the enzymes as in Feldman and as taught by these references, and it would have been obvious to aim at obtaining a high degree of hydrolysis. It would have also been obvious to follow the course of the hydrolysis to determine the DH, to measure the peptide bonds cleaved (by the ninhydrin method) and to calculate and control the degree of hydrolysis and to terminate the hydrolysis when the desired DH is reached. Therefore, the DH claimed would have been determinable and controlled to the extent required by the artisan, and given the teachings of the secondary references, this would have been within the ambit of the routineer.

Response to Arguments

Applicant's arguments filed 4/13/2010 have been fully considered but they are not persuasive.

Fish protein hydrolysates have been used in prior art for the feeding of calves, pigs, fish and other animals. See Simpson et al. The hydrolysates provide a number of benefits such as a beneficial source of peptones, providing immunostimulation, and yet,

there was a need for producing proteins that were not bitter and were of better quality. Feldman provides that choice of proteases that produces bland and soluble hydrolysates. Therefore, it would have been obvious to make such a combination (as above) in order to produce a better quality hydrolysate. Applicant's argument that Feldman does not disclose that the protein was for animals is therefore, of little weight. Next, applicant has pointed to the references chosen by applicant to show that the protein hydrolyzates of these references did not produce increased growth. Such an argument is unconvincing for the following reasons: 1) Applicant's claims are to "an animal" and then particularly to fish, and a variety of fishes (claim 33). The references show only certain fishes and the fact that applicant has pointed to these hand-picked references, even in the face of references such as Simpson et al. that shows that protein hydrolysates were already being provided to calves and weaning piglets, appears to be contradictory and unconvincing. Again, the claim is to a wider variety of animals *and* includes fishes, and one swallow does not make a summer. It is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims. See *In re Hyson*, 172 USPQ 399, *In re Tiffin*, 171 USPQ 294, *In re Lindner*, 173 USPQ 3562. The same argument holds good for applicant's showing of increased salmon growth in his examples when fed the inventive composition, which does not support the entire gamut of animals claimed. 3) Further, see MPEP 2144:

>IV. < RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary

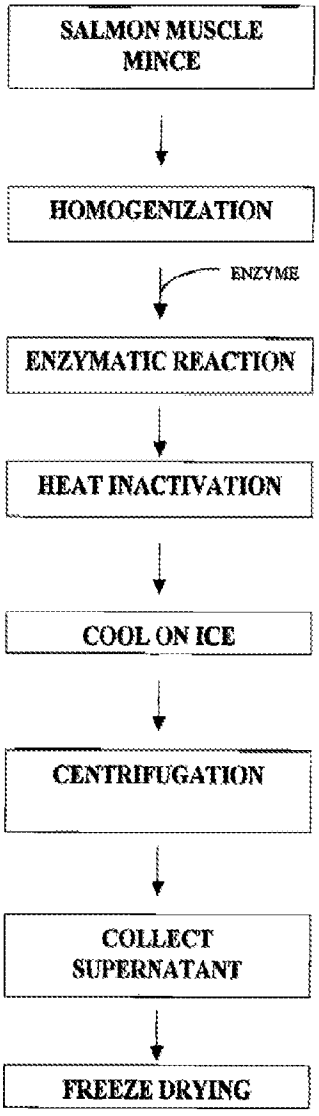
that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), *cert. denied*, 500 U.S. 904 (1991).

Therefore, it was known to make protein hydrolyzates from raw fish (see also the diagram below), it was known to feed animals including fish, with such proteins, it was known to hydrolyze fish with alkaline and neutral proteases (Feldman).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kristinsson et al. cited but not applied, shows a general method of enzymatic hydrolysis of salmon mince to produce fish protein hydrolysate. Figure 1:



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala, whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1781